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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,562	06/24/2003	**Michael N. Alekshun**	PAZ-190RCE	8041

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
09/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,562	ALEKSHUN ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 52* is/are pending in the application.

4a) Of the above claim(s) *7-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 15 November 2007 after a Final action mailed 18 June 2007 and an Advisory Action mailed 17 October 2007. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 18 June 2007 has been withdrawn pursuant to 37 C.F.R. §1.114. Applicants' submission and the R.C.E. filed 16 June 2008 have been entered. Accordingly an R.C.E. has been established and the action on R.C.E. follows.

2. The response and amendment filed 16 June 2008 is acknowledged and entered.

3. The appreciation regarding the interview conduced on 15 November 2007 with the participation of the undersigned Examiner, the Primary Patent Examiner and the applicants' Representatives is also acknowledged.

Claims Status

4. According to the amendments filed 16 June 2008 following is the status of Claims in the instant application:

- Claims 1-52 are currently pending;
- Claims 1, 5-6 and 52 have currently been amended;
- Claims 7-51 have been withdrawn; and
- Claims 1-6 and 52 are currently under examination on merits.

Withdrawn Claims

5. Claims 7-51 withdrawn from further consideration pursuant to 37 C.F.R. §1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 May 2006.

Information Disclosure Statement

6. The Information Disclosure Statement (i.e., IDS) filed 15 December 2007 is acknowledge,

entered, has been considered and duly initialed/signed copy of appropriate U.S. form is enclosed with the instant Office Action.

Claim Rejections - 35 U.S.C. §112

7. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

8. Claims 1-6 and 52 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the written description requirement rejection of Claims 1-6 and 52 under 35 U.S.C. §112, first paragraph in the Office Action mailed 18 June 2007, citing case laws applicants argue that "an objective standard for determining compliance with the written description requirement under 35 U.S.C. §112, first paragraph, is whether the specification conveys with reasonable clarity to those killed in the art that as of the filing date sought, the applicant was in possession of the invention as now claimed". Applicants further argue, "In particular, the Office Action, on page 5, states that "[t]he specification as currently presented while describing the treatment of a microbial infection via administering a modulator of a transcription factor to an individual in need thereof does not provide support for a method to prevent said infecting in an individual. Applicants traverse the foregoing rejection on the grounds that one of ordinary skill in the art would understand that Applicants were in possession of the claimed invention." In subsequent paragraphs (See Remarks filed 16 June 2008, Page 9 Line 18 to Page 12, Line 10), Applicants provide citations to different section of the presently filed specification, specifically making mention of the descriptions presented at pages 37, 127 and 132 of instant application and go on with a lengthy argument regarding, e.g., :

i. description of methods to administer compounds that downmodulate the expression or activity of a microbial transcription factor to a subject to reduce the virulence of the microbe;

ii. cell-free assays for screening inhibitors of the transcription factors;

iii. recitation of dosages given to mice in animal experimental models at the time of urinary tract infection in said mice; and

iv. application of a single subcutaneous dose of the inhibitor at the time of infection in pyelonephritis model.

The assertions presented in the remarks (See, Remarks filed 16 June 2008, Page 9 Line 18 to Page 12, Line 10) are:, e.g., "The Data Presented in the Application Demonstrates Prevention of Kidney Infection (Remarks filed 16 June 2008, Page 10, Line 19). However, in all of the examples given, a compound has not been identified that convincingly demonstrates prevention of infection, only statement, "compound can be identified" has been made even where an experiment has been described (e.g., Page 37, Lines 31-33; Page 38, Line 14). Additionally, statements made are futuristic events, e.g., "can be" (e.g., specification, Page 32, Lines 5, 12, 19, 26, 30, 32; Page 131, Line 23), "data will be used" (e.g., Page 128, Example 9), or "transcription factor modulator can penetrate" (Page 131, Line 28), or "assays can be performed (Page 38, Lines 2-3) rather than a showing that the experiments or events described were "actually reduced to practice".

Furthermore, the art- recognized practice for a clear cut demonstration of a prevention by a compound of any pathology or infection is to first administer the target compound and subsequently after a period of interval, administer a challenge of the organism whose infection or colonization is to be prevented. In contrast, the specification as currently presented describes concurrent administration of target preventive compound and the bacterial organism (e.g., Page 132, Lines 28-31, especially, Line 31). Additionally, some of the examples given are "treatment" rather than "prevention" because, e.g., in the kidney model, the bacterial infection is first established and subsequently the "downmodulating compound" is administered (Remarks filed 16 June 2008, Page 10, Lines 19-30). Similarly, in Figure 10, the showing is the effect on *Escherichia coli* by subcutaneous administration of the "downmodulator (i.e., compound 1, Remarks filed 16 June 2008, Page 11, Line 9). Also the data shown at page 127 clearly is from a "treatment" experiment as stated in the caption statement (Page 127, Line 6) above the Table on Page 127.

Applicants' arguments regarding the *in vitro* cellular assay methods, or the dosage regime, or transcription factors validated as targets for e.g., are directed to subject matter that is not encompassed in the claimed invention in Claims 1-6 and 52. Thus, applicants have made arguments not regarding the claimed invention, rather regarding all the non-related unclaimed subject matter, whereas "the invention is the subject matter defined in the claims" (See *In re Priest,* 199USPQ 11*).*

Applicants' arguments filed 16 June 2008 in regard to rejection to Claims 1-6 and 52 under 35 U.S.C. §112, first paragraph in the Office Action mailed 18 June 2007 have been carefully and fully considered, but as discussed *supra* they are not persuasive. Therefore, said rejection under 35 U.S.C. §112, first paragraph with regard to written description requirement is maintained and adhered to for the reasons of record at Pages 3-5, items 7-8 of the Office Action mailed 18 June 2007 and discussion presented *supra*.

New Matter

9. On the basis of amendments to Claims 1, 5-6 and 52 in the response filed16 June 2008, the following is a new rejection under 35 U.S.C. §112 first paragraph.

10. Claims 1-6 and 52 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as currently prescreened fails to recite a "A method for preventing infection of a subject by a microbe comprising: administering a compound that downmodulates the expression or activity of a microbial transcription factor to a subject at risk of developing an infection, wherein said downmodulation of the microbial transcription factor reduces virulence of the microbe, such that infection of the subject is prevented (i.e., each of Claims 1, 5-6 and 52 at Line 2; and each of Claims 1 and 52 at Line 4).

From the record of the presently filed written disclosure, the specification does not teach adequate support for the claimed "downmodulates" or "downmodulation" (See, e.g., Specification, Page 132, Lines 10 and 31, where the claimed word is "modulator". Furthermore, new matter can't be added in a claim.

Conclusion

11. For the aforementioned reasons, no Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber, can be reached on (571)-272-0295 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657
Kailash C. Srivastava, Ph.D.
Patent Examiner
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11 September 2008
/David M. Naff/
Primary Examiner, Art Unit 1657